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EXAMINER

SWOPE, SHERIDAN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,393

Applicant(s)

GRUBER ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 8-15, 18-43 and 46-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-7, 16, 17, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1003:0104</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election, with traverse, of Invention I, Claims 1-8, 13-18, 42-45, and 49, as well as the sub-invention of SEQ ID NO: 3, in their response of November 23, 2005 is acknowledged. The traversal is on the grounds that, since Invention III recites a method of treatment using the elected product, no undue burden would be imposed by examination of all the claims of Inventions I and III. This is not found persuasive. The MPEP states: "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02" (see MPEP 803). For the reasons explained in the prior action, Inventions I and III are distinct, as reflected by their different classifications. Thus, searching both said inventions would be a burden on the Office.

Applicant is reminded that should the elected products claims of Invention I be found allowable, the methods of using said product, Invention III, that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, *In re* Ochiai, and *In re* Brouwer). However, withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

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Claims 1-58 are pending. Claims 2-4, 8-15, 18-43, and 46-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Claims 1, 5-7, 16, 17, 44, and 45 are examined on their merits.

Priority

The priority date of the instant invention is taken to be June 8, 2001, the filing date of provisional applications US60/298,089.

Abstract

The Abstract is objected to for “polypeptidess” on line 4, which should be “polypeptides”.

Specification-Objections

The specification is objected to for not claiming priority to the parent application, US10/165,442, now issued as US6,706,512.

The specification is objected to for containing hyperlinks. USPTO policy does not permit the USPTO, i.e, via an issued patent, to link to any commercial sites, since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. Hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not to be included in a patent application. (MPEP 608.01) The specification should be carefully checked and all URLs removed.

The specification is objected to for having blank spaces on page 27, line 28, and page 38, line, 3, where GenBank Accession Nos. belong.

The specification is objected to for having a large blank space on page 56.

Drawings

Figures 1, 3, 5, 11c, and 12, are objected to for the following reasons.

Figure 1 indicates that it represents SEQ ID NO: 1. However, the sequence of Figure 1 is 259 amino acids long, but SEQ ID NO: 1 is 295 amino acids long. Correction or clarification is required.

Figure 3 indicates that it represents SEQ ID NO: 3. However, the sequence of Figure 3 is 259 amino acids long, but SEQ ID NO: 3 is 295 amino acids long. Correction or clarification is required.

Figure 5 indicates that it represents SEQ ID NO: 5. However, the sequence of Figure 5 appears to be less than 888 residues long, but SEQ ID NO: 5 is 888 amino acids long. Correction or clarification is required.

The legend for Figure 11c states that the figure “illustrates the release of fibrinopeptides A (●) and B (○) by wild-type and variant thrombin WE (W215A/E217A)”. However, Figure 11c displays only two data curves, with both being labeled (●).

The legend for Figure 12 states that the figure “illustrates the progress curve of the hydrolysis of TR³³⁻⁶² (●) and the release of the product TR³³⁻⁴¹ (○) by wild-type and variant thrombin WE (W215A/E217A)”. However, Figure 12 displays only two data curves, with both being labeled (●).

Claims-Objections

Claims 5 and 6 are objected to for “ration”, which should be “ratio”.

Claims 44 and 45 are objected to for reciting non-elected subject matter.

Claim 44 is objected to for being dependent from a non-elected claim.

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 1, 5-7, 16, 17, 44, and 45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 5-7, 9, 10, 12, and 13 of US Patent 6,706,512. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1, 5-7, 16, 17, 44, and 45 herein and Claims 1, 5-7, 9, 10, 12, and 13 of 6,706,512 are both directed to polypeptide variants of any thrombin, wherein the variant has substitutions W²¹⁵A and E²¹⁷A and has at least 80% homology to SEQ ID NO: 3. The claims differ in that Claims 1, 5-7, 9, 10, 12, and 13 of 6,706,512 specifically recite the

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functional limitations of protein C-activating activity and reduced platelet activating and fibrinogen cleavage activities, while Claims 1, 5-7, 16, 17, 44, and 45 herein do not recite said functional limitations. The portion of the specification in 6,706,512 that supports the recited variants includes embodiments that would anticipate Claims 1, 5-7, 16, 17, 44, and 45 herein, e.g., variants of any thrombin, wherein the variant has substitutions W²¹⁵A and E²¹⁷A and has at least 80% homology to SEQ ID NO: 3, wherein the variant has protein C-activating activity and reduced platelet activating and fibrinogen cleavage activities. Claims 1, 5-7, 16, 17, 44, and 45 herein cannot be considered patentably distinct over Claims 1, 5-7, 9, 10, 12, and 13 of 6,706,512 when there are specifically recited embodiments that would anticipate Claims 1, 5-7, 16, 17, 44, and 45 herein. Alternatively, Claims 1, 5-7, 16, 17, 44, and 45 herein cannot be considered patentably distinct over Claims 1, 5-7, 9, 10, 12, and 13 of 6,706,512 when there are specifically disclosed embodiments in 6,706,512 that supports Claims 1, 5-7, 9, 10, 12, and 13 of that patent and falls within the scope of Claims 1, 5-7, 16, 17, 44, and 45 herein, because it would have been obvious to a skilled artisan to modify the methods of Claims 1, 5-7, 9, 10, 12, and 13 of 6,706,512 by selecting a specifically disclosed embodiment that supports those claims, i.e., variants of any thrombin, wherein the variant has substitutions W²¹⁵A and E²¹⁷A and has at least 80% homology to SEQ ID NO: 3, wherein the variant has protein C-activating activity and reduced platelet activating and fibrinogen cleavage activities, as disclosed in 6,706,512. One having ordinary skill in the art would have been motivated to do this, because such an embodiment is disclosed as being a preferred embodiment within Claims 1, 5-7, 9, 10, 12, and 13 of the prior patent.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44, and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “reduced” is a relative term in Claim 44, which renders the claim indefinite. The term “reduced” is not defined by the claim, i.e. reduced relative to what, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprized of the scope of the invention. Claim 45, as dependent from Claim 44, is indefinite for the same reason. For purposes of examination, it is assumed that the term “reduced” in Claim 44 is meant to mean that the effect of the variant thrombin on procoagulant and platelet activity activities is reduced compared to the wild-type thrombin or compared to activated protein C, as shown in Figure 7.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1, 5-7, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the thrombin variant set forth by SEQ ID NO: 3, does not reasonably provide enablement for any polypeptide that is a variant of any thrombin, wherein the variant has substitutions W²¹⁵A and E²¹⁷A and has at least 80% homology to SEQ ID NO: 3.

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The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 1, 7, and 16 are so broad as to encompass any polypeptide that is a variant of any thrombin, wherein the variant has substitutions W²¹⁵A and E²¹⁷A and has at least 80% homology to SEQ ID NO: 3, wherein the polypeptide has any or no activity. Claims 5 and 6 are so broad as to encompass any polypeptide that is a variant of any thrombin, wherein the variant has substitutions W²¹⁵A and E²¹⁷A and has at least 80% homology to SEQ ID NO: 3 and wherein the variant has a specific PA/FC ratio. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be

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tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the polypeptide set forth by SEQ ID NO: 3.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galye et al, 1993; Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 1, 7, and 16 which, encompasses all polypeptides that are variants of any thrombin, wherein the variant has substitutions W²¹⁵A and E²¹⁷A and has at least 80% homology to SEQ ID NO: 3. The specification does not support the broad scope of Claims 5 and 6 which, encompasses all polypeptides that are variants of any thrombin, wherein the variant has substitutions W²¹⁵A and E²¹⁷A and has at least 80% homology to SEQ ID NO: 35 and 6 and wherein the variant has a specific PA/FC ratio. The specification does not support the broad scope of Claims 1, 5-7, and 16 because the specification does not establish: (A) the function of all polypeptides that are variants of any thrombin, wherein the variant has substitutions W²¹⁵A and E²¹⁷A and has at least

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80% homology to SEQ ID NO: 3; (B) regions of the protein structure which may be modified without effecting the desired activity; (C) the general tolerance of the desired activity to modification of the protein structure and extent of such tolerance; (D) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of polypeptides with an enormous number of amino acid modifications of the protein set forth by SEQ ID NO: 3. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim 7 is further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated host cell transformed with a synthetic nucleic acid that expresses the polypeptide of SEQ ID NO: 3, does not reasonably provide enablement for host cells within a multicellular organism that have been transformed with the synthetic nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 7 is so broad as to encompass host cells transformed with specific nucleic acids, including cells in *in vitro* culture as well as cells within any multicellular organism. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of host cells broadly encompassed by the claims. While methods for transforming cells *in vitro* are well known in the art, methods for successfully transforming cells within complex multicellular organisms are not routine and are highly unpredictable (Cameron, 1997). Furthermore, methods for producing a successfully transformed cell within one multicellular organism are unlikely to be applicable to transformation of other types of multicellular organisms as multicellular organisms vary widely. However, in this case the disclosure is limited to only host cells *in vitro*. Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the use of host cells within a multicellular organism for the production of polypeptide. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, expression of genes in a particular host cell and having the desired biological characteristics is unpredictable the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). It is suggested that applicants limit the claims to “within an isolated host cell”.

Written Description

Claims 1, 7, and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of polypeptide variants of thrombin having W²¹⁵A and E²¹⁷A substitutions and having at least 80% homology with SEQ ID NO: 3. The specification does not contain any disclosure of the function of all said polypeptides. The genus of polypeptides that comprise these above variant molecules is a large variable genus with the potentiality of having many different activities. Therefore, many functionally unrelated polypeptides are encompassed within the scope of these claims, including partial protein sequences. The specification discloses the function of only a two species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-7, 16, 17, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibbs et al, 1996 (IDS) in view of Arosio et al, 2000 (IDS) or Ayala et al,

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2001 (meeting date August 23-26, 2000). Gibbs et al teach a recombinant human thrombin variant having an E²¹⁷A substitution (designated E²²⁹A therein). Said variant has an enhanced PA/FC ratio, compared to wild-type thrombin (pg 413, para 1). Gibbs et al also teach a physiologically acceptable composition comprising said variant and instructions for administration to an animal (Fig 2). Gibbs et al, do not teach a human thrombin variant comprising both W²¹⁵A and E²¹⁷A substitutions. Each of Arosio et al (Table 1) and Ayala et al (Table 1) teach a human thrombin variant comprising a W²¹⁵A substitution, wherein the variant has reduced fibrinogen cleavage. It would have been obvious to a person of ordinary skill in the art to combine the teachings of Gibbs et al with either Arosio et al or Ayala et al to prepare a human thrombin variant comprising both W²¹⁵A and E²¹⁷A substitutions. Suggestion to do so is provided by Arosio et al, wherein they state that W²¹⁵ and E²¹⁷ are known to be important for thrombin function (pg 8100, para 1). Furthermore, suggestion and motivation to combine is based on the skilled artisan's desire to provide a thrombin variant with enhanced protein C activation and decreased fibrinogen cleavage, which would be useful as an anticoagulant for treatment of thrombolytic diseases. The expectation of success is high, as recombinant methods for producing variant proteins are well known in the art. Therefore, Claims 1, 5-7, 16, 17, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibbs et al, 1996 in view of Arosio et al, 2000 or Ayala et al, 2001.

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate

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pages. It is also requested that Applicants identify support, within the original application, for any amendments to the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
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SHERIDAN SWOPE, Ph.D.
PATENT EXAMINER